PATENT COOPERATION TREATY

From	the	INTER	RNAT	IONAL	BUREAU
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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT Washington, D.C.20231 ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)
02 May 2000 (02.05.00)

International application No.
PCT/US99/19436

International filing date (day/month/year)
30 August 1999 (30.08.99)

Applicant

EDMONDS, Brian, Taylor

	The deficiency of Office is however, a stiffer define election mode.
1.	The designated Office is hereby notified of its election made:
	X in the demand filed with the International Preliminary Examining Authority on:
	03 March 2000 (03.03.00)
	in a notice effecting later election filed with the International Bureau on:
2.	The election X was
	was not
	made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Faccimile No - (41.22) 740 14 35

Authorized officer

Pascal Piriou

Telephone No : (41-22) 338 83 38

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PATENT COOPERATION TREAT

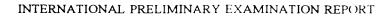
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference X-12239		otification of Transmittal of International ary Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/month/year)	·
PCT/US99/19436	30 AUGUST 1999	01 SEPTEMBER 1998
nternational Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and IPC	
Applicant ELI LILLY AND COMPANY		
Examining Authority and is 2. This REPORT consists of a	s transmitted to the applicant according total of sheets.	epared by this International Preliminary to Article 36.
been amended and are to (see Rule 70.16 and Sec	he basis for this report and/or sheets contained tion 607 of the Administrative Instruction	ining rectifications made before this Authority.
These annexes consist of a	ons relating to the following items	
I X Basis of the report II Priority III X Non-establishme IV Lack of unity of V X Reasoned statement citations and exp VI Certain document VII Certain defects in	ent of report with regard to novelty, invention ent under Article 35(2) with regard to novelanations supporting such statement	rentive step or industrial applicability velty, inventive step or industrial applicability
Date of submission of the demand	Date of comple	etion of this report
03 MARCH 2000	21 NOVEM	MBER 2000
Name and mailing address of the IPEA Commissioner of Patents and Trad Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		rea Saurence for (703) 308-0196



International application No.

PCT/US99/19436

I.	Ba	sis o	f the repor	-t			
1. \	With	regan	d to the elem	ents of the internation	onal application:*		
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L	x		claims:	62.67			
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	the i	nterna e eler	ational application applicatio	cation was filed, un vailable or furnishe	lless otherwise indicated to this Authority in	ted under this item.	which is:
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L	_	the la	anguage of	publication of th	e international app	olication (under Rule 48.3(b))).
	_	the la or 55.	-	ne translation furnis	shed for the purpose	s of international preliminary ex-	amination (under Rules 55.2 and/
						ce disclosed in the internationathe sequence listing:	al application, the international
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		The s	statement the	at the subsequentl lication as filed h	y furnished written as been furnished	sequence listing does not go b	beyond the disclosure in the
		The s been	tatement tha furnished.	t the information r	ecorded in computer	readable form is identical to th	e writen sequence listing has
4.	x	The .	amendment	s have resulted i	n the cancellation	of:	
	_	X	the descrip	ption, pages	NONE		
		X	the claims	, Nos.	NONE		
		x		ngs, sheets/ fig	NONE		
5. [7				me of) the amendme	mts had not been made, since the	ni hava baan aansidasad ta as
- · [emental Box (Rule 70.2(c)).**	y have ocen considered to go
i	n thu	cemer	nt sheets whice ort as "origi	ch have been furnisi	hed to the receiving (Office in response to an invitation is report since they do not con	under Article 14 are referred to Itain amendments (Rules 70.16
**	Any	replac	cement sheet	t containing such a	amendments must be	referred to under item 1 and a	annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/19436

III.	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
1. The	e questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be lustrially applicable have not been and will not be examined in respect of:
	the entire international application.
x	claims Nos. 8, 9, 13, 15-31
	because:
	the said international application, or the said claim Nos. relate to the following subject matter which does not require international preliminary examination (specify).
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify).
	the claims, or said claims Nos _ are so inadequately supported by the description that no meaningful opinion could be formed.
×	no international search report has been established for said claims Nos. 13, 15-31.
2. A	meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid quence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
	the written form has not been furnished or does not comply with the standard.
	the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/19436

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1.	statement			
	Novelty (N)	Claims Claims	1-3, 5-7, 10-12, 14 4	YES NO
	Inventive Step (IS)	Claims Claims	NONE 1-7, 10-12, 14	YES NO
	Industrial Applicability (IA)	Claims Claims	1-7, 10-12, 14 NONE	YES NO

2. citations and explanations (Rule 70.7)

Claims 1-3, 5-7, 10-12, 14 meet the criteria set out in PCT Article 33(2), because a single prior art reference does not teach or fairly suggest the claimed polypeptides or polynucleotides.

Claims 1-7, 10-12, 14 meet the criteria set out in PCT Article 33(2)and(4), because the claimed polypeptides or polynucleotides have utility in the biotechnology industry.

Claim 4 lacks novelty under PCT Article 33(2) as being anticipated by Database GenBank Accession No. AF011407. Database GenBank Accession No. AF011407 teaches an isolated nucleic acid molecule that hybridizes under stringent conditions to the complement of SEQ ID NO:1.

Claims 1-7, 10-12, 14 lack an inventive step under PCT Article 33(3) as being obvious over YIN in view of Database GenBank Accession No. AAB64201 and Database GenBank Accession No. AF011407. YIN teaches the cloning of a mouse LTBP-3 precursor (page 10149, column 1, full paragraph 1). YIN's mouse LTBP-3 cDNA is 86.5% identical at the nucleotide level to SEQ ID NO: 1 of the instant invention. The predicted polypeptide is 87.5% identical at the amino acid level to SEQ ID NO:2 of the instant invention. YIN also teaches vectors comprising the mouse LTBP-3 cDNA, host cells comprising the vector, a method of producing the encoded polypeptide, and the isolated polypeptide (page 10148, column 2, full paragraphs 3-5; page 10158, Figure 7). YIN also teach isolation of fragments of the human LTBP-3 gene and the coding sequence thereof (paragraph bridging pages 10157-10158). YIN also teaches it will be important to determine if LTBP-3 binds calcium and other molecules (page 10159, full paragraph 2). YIN is silent with respect to the amino acid and nucleotide sequence of the human LTBP-3. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to clone the human LTBP-3 cDNA with a reasonable expectation of success, using techniques such as those used by LIN for the cloning of the mouse LTBP-3 cDNA. One of ordinary skill in (Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/19436

Supp	lemental	Box
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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): C07K 14/47; C07H 21/04; C12N 1/21, 15/00; C12P 21/00 and US C1.: 530/350; 536/23.5; 435/7.1, 69.1, 252.3, 320.1

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

the art would be motivated to clone the human LTBP-3 cDNA for the recombinant production of the encoded human LTBP-3 polypeptide or analysis of expression of the human LTBP-3 mRNA in tissues. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to recombinantly express the encoded human LTBP-3 polypeptide with a reasonable expectation of success, using techniques such as those used by LIN for the recombinant expression of the mouse LTBP-3 polypeptide. One of ordinary skill in the art would be motivated to express the human LTBP-3 polypeptide recombinantly because the supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in (E. coli, bacteria, yeast, etc.) would provide a more abundant source of the human LTBP-3 polypeptide. Recombinant expression would provide a convenient source of readily purified protein. The human LTBP-3 polypeptide comprises at least 20 contiguous amino acids of the instantly disclosed SEQ ID NO:2, as evidenced by Database GenBank Accession No. AAB64201. The human LTBP-3 cDNA can hybridize to the instantly disclosed SEQ ID NO:1, as evidenced by Database GenBank Accession No. AF011407. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to test for the binding of the human LTBP-3 polypeptide to calcium or other compounds because YIN suggests that importance of doing so.

	NEW	CITATIONS	
NONE			

INTERNATIONAL SEARCH REPORT

International application No. PCT/US99/19436

A. CLASSIFICATION OF SUBJECT MATTER	21/60
IPC(7) ::CO7K 14/47; C07H 21/04, C12N 1/21, 15/00, C12P US CL ::530/350, 536/23.5, 435/7.1, 69.1, 252.3, 320 1	21700
According to International Patent Classification (IPC) or to both	national classification and IPC
B. FIELDS SEARCHED	
Minimum documentation searched (classification system follower	d by classification symbols)
U.S 530/350; 536/23.5, 435/7.1, 69.1, 252.3, 320.1	
Documentation searched other than minimum documentation to the	extent that such documents are included in the fields searched
Electronic data base consulted during the international search (na	ime of data base and, where practicable, search terms used)
WEST, CAPLUS search terms: latent TGF-beta binding protein, LTBP	
C. DOCUMENTS CONSIDERED TO BE RELEVANT	
Category* Citation of document, with indication, where ap	propriate, of the relevant passages Relevant to claim No
Y YIN et al. Isolation of a novel laten beta-binding protein (LTBP-3). J. Biol 270, No. 17, pages 10147-10160, espe paragraph 1; paragraph bridging page col. 2, last paragraph.	. Chem. 28 April 1995, Vol. cially page 10148, col. 1, full
GONG et al. Isoforms and splice va factor beta-binding protein in r Gastroenterology. February 1998, Vol especially page 352, paragraph bridging 1, full paragraph 1; page 357, paragra	at hepatic stellate cells 114, No. 2, pages 352-363, g columns 1-2; page 353, col.
X Further documents are listed in the continuation of Box C	. See patent family annex
Special categories of cited documents	*T* lister document published after the international filing date or priority date and not in conflict with the application but cited to understand
"A" document defining the general state of the art which is not considered to be of particular relevance.	the principle or theory underlying the invention
E earlier document published on or after the international filing date	*X* document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other	*Y* document of particular relevance, the claimed invention cannot be
special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means	considered to invoive an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
P document published prior to the international filing date but later than the priority date claimed	*&* document member of the same patent family
Date of the actual completion of the international search	Date of mailing of the international search report
25 JANUARY 2000	11 FEB 2000
Name and mailing address of the ISAUS Commissioner of Patents and Trademarks Box PCT	Authorized wincer Jaurence Tox DAVID'S ROMEO
Washington, D.C. 20231 Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196



International application No. PCT US99/19436

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Ý	Database GenBank, US National Center for Biotechnology Information, (Bethesda, MD, USA), Accession No. AF011407, MICHEL et al. 'Analysis of the expression pattern of the latent TGF-beta binding protein (LTBP) isoforms in normal and diseased human liver reveals a new splice variant missing part of the proteinase sensitive hinge region', 28 July 1997.	1-7, 10-12, 14
Y	Database GenBank, US National Center for Biotechnology Information, (Bethesda, MD, USA), Accession No. AAB64201, MICHEL et al. 'Analysis of the expression pattern of the latent TGF-beta binding protein (LTBP) isoforms in normal and diseased human liver reveals a new splice variant missing part of the proteinase sensitive hinge region', 28 July 1997.	1-7, 10-12, 14





International application No. PCT/US99/19436

Box I. Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)				
This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:				
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:				
Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically				
3 X Claims Nos: 8-9 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)				
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)				
This International Searching Authority found multiple inventions in this international application, as follows:				
Please See Extra Sheet.				
As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.				
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.				
As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:				
4. X No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos: 1-7, 10-12				
Remark on Protest The additional search fees were accompanied by the applicant's protest				
No protest accompanied the payment of additional search fees.				





International application No. PCT/US99/19436

BOX II OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-12, 14, drawn to human LTBP-3 polypeptides and polynucleotides

Group II, claim(s) 13, 17, drawn to an antibody that binds a human LTBP-3.

Group III, claim(s) 15, 16, 18-20, 25, drawn to a method of administering a human LTBP-3 polypeptide to a patient Group IV, claim(s) 21, drawn to a method of administering a compound that binds a human LTBP-3 polypeptide to a patient.

Group V, claim(s) 22-24, 26-28, to the extent that they are drawn to a method of modulating the expression of a human LTBP-3 polynucleotide.

Group VI, claim(s) 22-24, 26-28, to the extent that they are drawn to a method of modulating the activity of a human LTBP-3 polynucleotide.

Group VII, claim(s) 29-31, to the extent that they are drawn to a method of manufacturing a medicament comprising a compound that modulates the expression of a human LTBP-3 polynucleotide

Group VIII, claim(s) 29-31, to the extent that they are drawn to a method of manufacturing a medicament comprising a compound that modulates the activity of a human LTBP-3 polynucleotide

The inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons

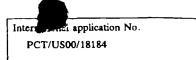
The special technical feature of the main invention, Group I, is a human LTBP-3 polypeptide. In order for unity of invention to be present the claims must define a special technical feature that makes a contribution over the prior art. However, YIN et al. teach the existence of the human LTBP-3 gene and the isolation of fragments thereof. See the paragraph bridging pages 10157-10158. The human LTBP-3 polypeptide comprises at least 20 contiguous amino acids of SEQ ID NO.2, as recited in claim 1, as evidenced by GenBank database entry accession no. 015107. Accordingly, group I does not fulfill the requirements of unity of invention with respect to a human LTBP-3 polypeptide. Any of groups II-VIII do not share a special technical feature with group I because group I does not have a special technical feature.

Pursuant to 37 CFR 1.475(d), this authority considers that where multiple products and processes are claimed, the first recited product, method of making that product, and method of using that product, together with the first recited of each of the other inventions related thereto, shall constitute the main invention. Further, it considers that any subsequently recited products and/or methods constitute separate groups. Accordingly, groups II-VIII constitute separate groups.

Interritation No.
PCT. 0000/18184

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) :C07K 14/47; C07H 21/04; C12N 15/63, 1/21; C12P 21/02 US CL : 530/350; 536/ 23.5; 435/320.1, 252.3, 69.1 According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
Minimum documentation searched (classification system followed by classification symbols)				
U.S. : 530/350; 536/ 23.5; 435/320.1, 252.3, 69.1				
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Extra Sheet.				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.	
X 	molecular family conserved throughout vertebrates. Eur. J. Immunol.		1, 3-5, 8, 12 6, 7, 10	
Y 	acid sequences, and the attached sequence alignment which shows a			
Α	100% identical match to amino acids 21-100 of SEQ ID NO:2. 2, 9			
X Y A	Sequence Database EST, National Cancer Institute, Cancer Genome Anatomy Project (CGAP), Tumor Gene Index, AN AI478852. 'tm24f09.x1 Soares_NFL_T_GBC_S1 Homo sapiens cDNA clone IMAGE:2157545 3' similar to TR:Q91665 CTX;, mRNA sequence'.		1, 3-5, 8 6, 7, 10, 12 2, 9	
Further documents are listed in the continuation of Box C. See patent family annex.				
* Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention			lication but cited to understand	
"E" earlier document published on or after the international filing date		'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone		
aited to establish the mublication date of another citation or other		considered to involve an inventive	lar relevance; the claimed invention cannot be we an inventive step when the document is r more other such documents, such combination erson skilled in the art	
	document published prior to the international filing date but later than *A.* document member of the same patent family the priority date claimed			
Date of the actual completion of the international search Date of mailing of the international search			earch report	
31 AUGUST 2000 22 SEP 2000			100 11	
Commission Box PCT	mailing address of the ISA/US oner of Patents and Trademarks on, D.C. 20231	Authorized officer EILEEN B. O'HARA	l Bridgest	
-		Telephone No. (703) 368-0196	7	





Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)				
This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:				
1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:				
Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:				
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).				
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)				
This International Searching Authority found multiple inventions in this international application, as follows:				
Please See Extra Sheet.				
As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.				
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.				
As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:				
No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-10 and 12				
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.				



Internal application No.
PCT/US00/18184

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

Commercial Sequence Databases: GenEmbl, N_Geneseq_36, Issued_Patents_NA, EST, A_Geneseq_36,

Issued_Patents_AA, PIR_64, SwissProt_38STREMBL_12

Sequences searched: SEQ ID NOS: 1, 2 and 3

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-10 and 12, in so far as they are drawn to Tango 244, polynucleotides of SEQ ID NOS: 1 and 3, vector, host cell, method of producing a protein recombinantly and protein of SEQ ID NO:2.

Groups II-V, claim(s) 1-10 and 12, in so far as they are drawn to the next four polynucleotides of distinct cDNA clones and encoded proteins, identified as Tango 246, Tango 275, Tango 300 and human and monkey Mango 245.

Groups VI-X, claims 11 and 15, in so far as they are drawn to antibodies to one of the five proteins listed above. Groups XI-XV, claims 13, 14, 19, 20 and 22, in so far as they are drawn to a method for detecting the presence of in a sample or identifying a compound which binds to or modulates the activity of a polypeptide of one of the five proteins listed above.

Groups XVI-XX, claims 16 and 17, in so far as they are drawn to a method for detecting the nucleic acids of one of the five cDNA clones listed above.

Groups XXI-XXV, claim 18, in so far as it is drawn to a kit comprising a compound of unspecified constitution which selectively binds to a nucleic acid molecule of the five cDNA clones listed above.

Groups XXVI-XXX, claim 21, in so far as it is drawn to a method for modulating the activity of one of the five proteins listed above.

The inventions listed as Groups I-XXX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I corresponds to the first invention wherein the first product is the polynucleotide and the first method of using is the method of making the protein. Note that there is no method of making the polynucleotide. The invention also includes the protein made. Each of groups II-V does not share the same or corresponding special technical feature because each group is drawn to a different polynucleotide and encoded protein, and each of groups VI-XXX does not share the same or corresponding special technical feature because each group is drawn to different compounds or methods of using the five polynucleotides and encoded proteins. This Authority therefore considers that the several inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.